



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/708,919

03/31/2004

Mark C. Boomer

101896-0241

2918

21125 7590 02/19/2010  
NUTTER MCCLENNEN & FISH LLP  
SEAPORT WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02210-2604

EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3733

NOTIFICATION DATE

DELIVERY MODE

02/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/708,919	<b>Applicant(s)</b> BOOMER ET AL.	
	<b>Examiner</b> DAVID COMSTOCK	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,10,13-20,42,43 and 46-50 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20 October 2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Drawings*

The drawings received on 04 November 2009 are accepted.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7, 10, 13-20, 42, 43 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (5,509,328) in view of Carden (6,284,014).

Lai discloses a device comprising a first elongate member 10 having a female connector with opposed arms 13 and a second elongate member 20 having a male connector 40 adapted to mate to the female connector (see Fig 2). The members are adjustably coupled to one another. A fastening element locks the elongate members in a fixed position. The devices are angularly adjustable in a single plane. The opposed arms define a recess for receiving the male connector. The device includes a bore 14 extending through the opposed arms on the female connector and through the male connector, and a central mating element 51, 52 extending through the bore for mating the male and female connectors together. The central mating element comprises a cylindrical member 51. The device rotates about this member when it is in a loosened state. The cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member when loose. The

Art Unit: 3733

fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector when tightened. The fastening element comprises a slot 43 extending through the male connector such that the male connector is in the form of a clamp, and wherein the device further comprises a threaded fastener 44 adapted to engage and mate with the male connector to clamp the cylindrical member within the bore. The female connector and male connector rotate about a central axis extending substantially perpendicular to an axis of the first and second elongate members. The fastening element is adapted to extend into a connector along an axis that is substantially parallel to the plane of adjustability. The diameter of the first and second elongate member appears to be generally the same with the diameter of portion 20 being only slightly larger than that of portion 10. A terminal end of the second elongate member (e.g., the flush surface that mates with portion 32) is at a 90 degree angle to a longitudinal axis of the second elongate member. Lai does not explicitly recite the material from which the device is formed. However, Carden teaches a matrix alloy composition comprising titanium that can advantageously be used in both bicycles and in medical implants in order to provide increased rigidity and strength and decreased weight (see, e.g., col. 1, lines 15-34; col. 4, lines 5-41; and col. 16, lines 15-17). It would have been obvious to have formed the device of Lai from a matrix alloy composition comprising titanium, in order to make the device stronger, more rigid and lighter. The resulting structure would inherently be biocompatible. Moreover, it also would have been obvious to have formed the device of Lai from, e.g., titanium, since it has been held to be within the general skill of a worker in

Art Unit: 3733

the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is noted that titanium is a common material for devices of the type set forth by Lai for its light weight and strength and titanium is also a widely recognized biocompatible material for medical implants. Screws 35 and 36 are anchors and are capable of being secured to spinal bone.

### ***Allowable Subject Matter***

Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed 04 November 2009 have been considered but are not fully persuasive.

Regarding the Yue reference, Applicants arguments corresponding to the amended claims are persuasive for the reasons advanced by Applicant (see, e.g., page 8, lines 3-6).

Regarding the Lai reference, Examiner maintains the rejection. A comparison of the device of Lai (see, e.g., Fig. 2) and that of Applicant (see, e.g., Fig. 1A) show effectively identical structure. Even the material from which devices such as that disclosed by Lai are commonly formed (e.g., titanium) is a well-known implant material. Given that a patent directed to an apparatus should not be given simply for a new use of old structure, and the only possible differences between the applied art and Applicant's

Art Unit: 3733

invention are at most some minor alleged difference between certain grades of titanium, and an intended use, the rejection is maintained. Applicant has not presented any evidence that screws 35 and 36 somehow would not be capable of being used with bone. There is no "standard" bone screw and there is nothing to prevent screws 35 and 36 from, for example, passing through or being attached to a hole in bone such as in a portion of a spine. Regarding the biocompatibility of the material disclosed in Carden, a "prosthesis" is a device that replaces internal and external body parts and therefore encompasses implantable medical devices. Moreover, the statement in Carden that strength and light weight are important for medical applications (see, e.g., col. 16, lines 15-17) further supports the fact that a prosthesis refers to devices that replace both internal and external body parts. It is also noted that Applicant alleges that "ASTM recognizes 38 different grades of titanium alloy, not all of which are biocompatible and/or suitable for implantation" but does not produce any evidence of the same in the reply.

Finally, the device of Lai as modified is reasonably considered analogous art. See, for example, *Stevenson v. International Trade Comm.*, 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979) ("In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas"). See also *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004). The prior art is in the field of adjustable structures, like the invention of Applicant. Moreover, the reference has effectively identical structure, so it cannot be asserted that it somehow is not reasonably pertinent to the particular problem with which the inventor was involved. That Lai as modified is intended to be used in a different application and

Art Unit: 3733

might be classified in another location does not equate to non-analogy. Quite the contrary, the courts have found that "the similarities and differences in structure and function of the inventions **carry far greater weight**" than where the inventions may be classified. (emphasis added by Examiner) *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973). (The structural similarities and functional overlap between references were readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant's invention dealt). Here, the structural similarities are beyond "readily apparent," they are striking. If a device as structurally similar to Applicant's device as that of Lai cannot be applied to reject the claims, it is unclear why "in a simple mechanical invention a broad spectrum of prior art must be explored" at all, as it was previously noted the courts have held. There would be no purpose in "exploring a broad spectrum of art" and "inquiring into other areas" if effectively identical art is discarded due merely to a different intended use, while other factors carry more weight. Therefore, as Applicant's device is a simple mechanical invention, the applied art can be seen as analogous, as set forth above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3733

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733